

REMARKS

Claims 1-31 were examined. Claims 1, 3 and 4 are amended. Claim 2 is canceled. Claims 1 and 3-31 remain in the Application.

The Patent Office objects to the drawings and claim 2. The Patent Office rejects claim 1 under 35 U.S.C. §102(b). The Patent Office rejects claims 2-31 under 35 U.S.C. §103(a). Reconsideration of the pending claims is respectfully requested in view of the above amendments and the following remarks.

A. Objection to Drawings

The Patent Office believes Figures 1-11 should be designated by a legend such as "Prior Art" because only that which is old is illustrated. Applicant submits herewith a replacement sheet for Figure 1. Figure 1 is labeled as "Prior Art." Applicant respectfully requests that the Patent Office enter the replacement sheet.

With respect to Figures 2-11, Applicant disagrees that such figures only illustrate that which is old. In fact, Figures 2-11 relate to the invention described in the Application and described in reference to the figures.

Applicant respectfully requests that the Patent Office withdraw the objection to the drawings.

B. Objection to Claim 2

The Patent Office objects to claim 2 because of an informality. Claim 2 is canceled rendering the objection moot.

C. 35 U.S.C. §102(b): Rejection of Claim 1

The Patent Office rejects claim 1 under 35 U.S.C. §102(b) as anticipated by U.S. Patent No. 6,102,904 of Vigil et al. (Vigil); U.S. Patent No. 5,941,868 of Kaplan et al. (Kaplan); U.S. Patent No. 5,354,279 of Hofling (Hofling); or U.S. Patent No. 5,464,396 of Faxon et al. (Faxon).

Claim 1 describes a method including positioning a delivery device at a location in a blood vessel; imaging a thickness of a portion of a wall of the blood vessel at the location; identifying a treatment site based on the imaging; advancing the delivery device into a wall of the blood vessel to the treatment site beyond an external elastic lamina of the blood vessel; and after advancing the delivery device, introducing a treatment agent through the delivery device. Claim 1 incorporates the limitation of claim 2.

Claim 1 is not anticipated by Vigil, Kaplan, Hofling or Faxon, because none of the references describe imaging a thickness of a portion of a wall of a blood vessel at a location and a identifying a treatment site based on the imaging.

Applicant respectfully requests that the Patent Office withdraw the rejection to claim 1 under 35 U.S.C. §102(b).

D. 35 U.S.C. §103(a): Rejection of Claims 2-31

The Patent Office rejects claims 2-9 under 35 U.S.C. §103(a) as obvious over Vigil, Kaplan, Hofling or Faxon in view of U.S. Patent No. 5,499,630 of Hiki et al. (Hiki). Vigil, Kaplan, Hofling and Faxon are cited for disclosing introducing a treatment agent beyond an external elastic lamina of a blood vessel. Hiki is cited for a catheter type ultrasound probe capable of forming ultrasound imaging and optical imaging of a region requiring treatment. Hiki discloses an ultrasound probe having an ultrasound transducer mounted on a girder portion of a rigid fore end section. What is described is an endoscopic ultrasound probe including rigid fore end section 6. See col. 4, lines 22-37. Rigid fore end section 6 is provided with endoscopic observation means 11 on distal end phase 6a including illumination window 10 and observation window 11. Disposed in illumination window 10 is a light emitting end of a light guard. A lens is fitted in observation window 11 to form an optical image of a predetermined plane where a solid-state image sensor is located to take out the images for endoscopic observation. See col. 4, lines 38-50. Mounted on rigid fore end section 6 is ultrasound transducer 20. See col. 4, lines 55-60. An ultrasound image is displayed so that puncture needle 30 may be launched to penetrate an intracavitary wall into a target portion which needs a therapeutic treatment or examination. See col. 6, lines 20-24. The example described relates to a stomach and inserting the catheter through the throat and esophagus. See col. 5, lines 49-56.

Claims 1 and 3-9 are not obvious over the cited references, because the references fail to describe positioning a delivery device in a blood vessel and imaging a portion of a wall of the blood vessel at a location with an imaging assembly disposed in a lumen of a delivery device. As noted above, the ultrasound probe of Hiki is directed at endoscopic examination/treatment and has its imaging device described as an ultrasound transducer on a rigid fore end section of the probe. Thus, Hiki does not describe an imaging assembly disposed in a lumen of a delivery device. As an endoscope device, Hiki describes its probe in relation to introduction in body cavities through, for example, the esophagus. Hiki does not describe routing a device through a blood vessel. In one sense, Hiki is on a scale potentially much larger than the scale to which the pending claims are directed. Thus, one would not look to Hiki for teachings, suggestions or motivations for imaging a thickness of a portion of a wall of a blood vessel. Further, Hiki describes an imaging device on a rigid fore end section. A rigid fore end section may be suitable for endoscopic operations but snaking a rigid device through one or many blood vessels presumably would be much more challenging.

Applicant respectfully requests that the Patent Office withdraw the rejection to claims 2-9 under 35 U.S.C. §103(a).

E. 35 U.S.C. §103(a): Rejection of Claims 10-27

The Patent Office rejects claims 10-27 under 35 U.S.C. §103(a) as obvious over Kaplan in view of U.S. Patent No. 5,540,912 of Roorda et al. (Roorda) or U.S. Patent No. 5,575,815 of Slepian et al. (Slepian).

Claims 10-14 depend from claim 1 and therefore contain all the limitations of that claim. For at least the reasons stated above, claims 10-14 are not obvious over the cited references. The references are directed at their teachings of therapeutic agents. Specifically, Roorda is cited for teaching controlled-release therapeutic agents and Slepian for therapeutic agents not taught in Kaplan.

In addition to being dependent on independent claim 1, Applicant is unable to find teachings in the cited references directed at carriers comprising particles having an average diameter on the order of 10 microns or less (claim 10); the carrier includes an opsonin-inhibitor

(claim 11); a treatment agent that induces an inflammation-inducing response (claim 12); or a treatment agent that includes a thermally conductive material and a method including heating the treatment agent (claim 13). For these additional reasons, Applicant believes the noted claims are not obvious over the cited references.

Claims 15-22 describe a composition comprising an inflammation-inducing agent, wherein the composition has a particle size suitable for transvascular delivery. Applicant is unable to find any teaching in the cited references of Kaplan, Roorda, or Slepian that teaches an inflammation-inducing agent. Slepian teaches anti-inflammatories. See col. 7, lines 29-30. Roorda also teaches therapeutic agents that may be anti-inflammatory. See col. 5, lines 34-36. Kaplan teaches growth factors. See col. 2, line 62 through col. 3, line 4.

Claims 23-27 describe a composition including at least one treatment agent disposed in a carrier and an opsonin-inhibitor coupled to the carrier. Applicant is unable to find any teaching in Kaplan, Roorda or Slepian for specific teaching a carrier and an opsonin-inhibitor coupled to the carrier. Examples of an opsonin-inhibitor in the Application include polyethylene glycol and glycocalyx-like molecules. See Application, ¶¶ [0058]-[0062]. Applicant is unable to find any similar teachings in the cited references.

Applicant respectfully requests that the Patent Office withdraw the rejection to claims 10-27 under 35 U.S.C. §103(a).

F. 35 U.S.C. §103(a): Rejection of Claims 28-31

The Patent Office rejects claims 28-31 under 35 U.S.C. §103(a) as obvious over Hofling in view of Hiki. Hofling is cited for teaching an apparatus including a catheter, a dilatable balloon and at least one needle. Hiki is cited for teaching an ultrasound probe. As noted above, Hiki is directed at endoscopic treatment and thus places its ultrasound transducer on a rigid end of its probe.

Claims 28-31 describe an apparatus including a catheter body capable of traversing a mammalian blood vessel; a dilatable balloon; at least one needle body disposed within the catheter; an imaging body disposed within the catheter body and comprising a lumen having dimensions suitable for a portion of an imaging device to be advanced therethrough and adapted

to be shared simultaneously or sequentially with a guidewire; and a portion of an imaging device disposed within the imaging body adapted to generate imaging signals of the blood vessel.

Claims 28-31 are not obvious over the cited references, because the references do not describe, provide any motivation, suggestion, or prediction for a catheter body capable of traversing a mammalian blood vessel and including an imaging body disposed within the catheter body and having dimensions suitable for an imaging device to be advanced therethrough and adapted to be shared simultaneously or sequentially with a guidewire or a portion of an imaging device disposed within the imaging body adapted to generate imaging signals of the blood vessel. As noted above, Hiki is cited for the imaging feature of the combination. Hiki teaches an ultrasound transducer on a rigid end of its endoscopic device. There is no motivation for including an imaging device in, for example, a modified guidewire lumen.

Applicant respectfully requests that the Patent Office withdraw the rejection to claims 28-31 under 35 U.S.C. §103(a).

CONCLUSION

In view of the foregoing, it is believed that all claims now pending patentably define the subject invention over the prior art of record and are in condition for allowance and such action is earnestly solicited at the earliest possible date.

If necessary, the Commissioner is hereby authorized in this, concurrent and future replies, to charge payment or credit any overpayment to Deposit Account No. 02-2666 for any additional fees required under 37 C.F.R. §§ 1.16 or 1.17, particularly extension of time fees.

Respectfully submitted,

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Date:

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